| Requirement | Findings | Y/N |
| --- | --- | --- |
| 4 Context Of Your Company |  |  |
| 4.3 Determining the Scope of the Quality Management System |  |  |
| The scope of Your Company's quality management system shall be available and be **maintained as documented information**. The scope shall state the types of products and services covered and provide justification for any requirements of the standard that Your Company determines is not applicable to the scope of its quality management system. These are described in 1.2. |  |  |
| 4.4.2 |  |  |
| To the extent necessary, Your Company shall:   * **maintain documented information** to support the operation of its processes; * **retain documented information** to have confidence that the processes are being carried out as planned. |  |  |
| 5 Leadership |  |  |
| 5.2.2 Communicating the quality policy |  |  |
| The quality policy shall:   * Be available and be maintained as documented information; * Be communicated, understood and applied within Your Company; * Be available to relevant interested parties, as appropriate. |  |  |
| 6 Planning |  |  |
| 6.2.1 |  |  |
| The quality objectives are:   * Consistent with the quality policies; * Measurable; * Take into account applicable climate; * Be relevant to conformity of products and services and to enhancement of customer satisfaction; * Are monitored; * Communicated; * Updated as appropriate.   Your Company shall **maintain documented information** on the quality objectives. |  |  |
| 7 Support |  |  |
| 7.1.5.1 General |  |  |
| Your Company shall ensure that the resources provided:   * Suitable for the specific type of monitoring and measurement activities being undertaken; * Are maintained to ensure their continuing fitness for purpose.   Your Company shall **retain appropriate documented information** as evidence of fitness of purpose or a monitoring and measurement resources. |  |  |
| 7.1.5.2 Measurement and Measurement Traceability |  |  |
| When Measurement Traceability is a requirement, or is considered by Your Company to be essential part of providing confidence in the validity of measurement results. Measurement equipment shall be:   * Calibrated or verified or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; When no such standards exists, the basis used for calibration verification shall be **retained as documented information**. * Identified in order to determine their status: Typical * Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. |  |  |
| 7.2 Competence |  |  |
| Your Company has:Determined the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management systems;Ensure that these persons are competent on the basis of appropriate education, training or experience;Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;Retain appropriate documented information as evidence of competence.Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons. |  |  |
| 8 Operations |  |  |
| 8.1 Operational Planning and Control |  |  |
| Your Company plans, implements and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6 by:   * Determine the requirements for the products and services; * Establishing criteria for the processes and the acceptance of products and services; * Determining the resources needed to achieve conformity to product and service requirements; * Implementing control of the processes in accordance with the criteria; * Determining, maintaining and **retaining documented information** to the extent necessary:   1. To have confidence that the processes have been carried out as planned;  2. To demonstrate the conformity of products and services to their requirements. The output of this planning shall be suitable for Your Company's operations. |  |  |
| 8.2.3.2 |  |  |
| Your Company shall **retain documented information**, as applicable:   * On results of the review;  On any requirements for the products and services. |  |  |
| 8.3.3 Design and development inputs |  |  |
| Input shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. Your Company has retained documented information of design and development inputs. |  |  |
| 8.3.4 Design and development controls |  |  |
| Your Company has applied controls to the design and development process to ensure that:   * The results to be achieved are defined; * Reviews are conducted to evaluate the ability of the results of the design and development to meet requirements; * Verification activities conducted to ensure that the design and development efforts meet the input requirements, also; * Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; * Any necessary actions are taken on problems determined during the reviews, or verification of validation activities;  Documented information of these activities is retained. |  |  |
| 8.3.5 Design and development outputs |  |  |
| Your Company has ensured that design and development outputs:   * Meet the input requirements; * Are adequate for the subsequent processes for the provision of products and services; * Included are reference monitoring measuring requirements, as appropriate, and acceptance criteria; * Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.  Your Company has retained documented information on design and development outputs. |  |  |
| 8.3.6 Design and development changes |  |  |
| Your Company has retained documented information on:   * Design and development changes; * The results of review; * The authorization of changes; * The actions taken to prevent adverse impacts |  |  |
| 8.4.1 General |  |  |
| Your Company shall determine the controls to be applied to externally provided processes, products and services when:   * Products and services from external providers are intended for incorporation into Your Company's aim, products and services; * Products and services are provided directly to the customer by external providers on behalf of Your Company; * A process or part of a process provided by external provider as a result of a decision by Your Company; * Your Company shall determine and apply criteria for the evaluation, selection, monitoring of performance, and reevaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.   **Your Company shall retain documented information of these activities and any necessary actions arising from the evaluations.** |  |  |
| 8.5.2 Identification and traceability |  |  |
| Your Company shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability. |  |  |
| 8.5.3 Property Belonging to Customers or External Providers |  |  |
| Your Company shall report this to the customer or external provider and retain documented information on what has occurred. A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data. |  |  |
| 8.5.6 Control changes |  |  |
| Your Company shall retain documented information describing the results of the review of change, the personal persons authorizing the change, and any necessary actions arising from the review. |  |  |
| 8.6 Release of Products and Services |  |  |
| Your Company shall **retain documented information** on the release of products and services. The documented information shall include:   * Evidence of conformity with the acceptance criteria; * Traceability to the person/persons authorizing the release. |  |  |
| 8.7.1 |  |  |
| Your Company shall **retain documented information** that:   * Describes to low confirmatory; * Describes the actions taken; * Describes any concessions of time; * Identifies the authority deciding the action in respect of the conformity. |  |  |
| 9 Performance Evaluation |  |  |
| 9.2.1 |  |  |
| Your Company:   * plans, establishes, implements and maintains an audit program, including the frequency, methods, responsibilities, planning, requirements and reporting which shall take into consideration the importance of the process concerned, changes affecting Your Company, and the results of previous orders; * defines the order criteria and scope for each order; * selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process; * ensures that results of the audits are reported to the relevant management; * takes appropriate correction and corrective actions without undue delay; * **retains documented information** as evidence of the implementation of the audit program and the audit results. |  |  |
| 9.3.3 Management review outputs |  |  |
| The outputs of the management review include decisions and actions related to:   * opportunities for improvement; * any need for changes to the quality managed system; * resource needs.   Your Company **retains documented information** as evidence of the results of management reviews. |  |  |
| 10 Improvement |  |  |
| 10.2.2 |  |  |
| Your Company **retains documented information** as evidence of the:   * nature of the nonconformities and any subsequent actions taken; * results of any corrective action |  |  |